K960892

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K960892

APR 15 1996

1. **Applicant Name, Address**: W.L. Gore & Associates, Inc.
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2. **Classification Name**: Nonresorbable Barrier Membrane
Common or Usual Name: Regenerative Material
Proprietary Name: GORE-TEX Regenerative Material -- Titanium Reinforced Configurations

3. **Predicate Device**: GORE-TEX Periodontal Material -- Titanium Reinforced Configurations

4. **Device Description**:

The Titanium Reinforced Configurations of GORE-TEX Regenerative Material are designed to act in accordance with the accepted principles of wound healing and guided tissue regeneration (GTR). Specifically, the device is designed to be biocompatible, cell occlusive, spacemaking, and clinically manageable, and allow for tissue integration. The materials used in the manufacture of the Titanium Reinforced Configurations do not alter the biology of GTR therapy or the application for which the product is presently used.

GORE-TEX Regenerative Material is surgically placed beneath the muco-periosteum to aid in the regenerative healing of (1) bone or (2) bone/periodontal

ligament defects of the oral cavity. The material is designed to be a passive barrier which excludes epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur.

The material is designed to be stiff enough to create and maintain a protected defect space into which new hard and soft tissues can form, but supple enough to drape smoothly over the defect margin. It is non-absorbable, thereby allowing for predictable isolation of the defect site.

5. **Intended Use**:

GORE-TEX Regenerative Material is intended to provide a mechanism for the ingrowth of new hard and soft tissues into bony defects surrounding teeth and to augment ingrowth of hard and soft tissues on alveolar ridges. GORE-TEX Regenerative Material is a passive, non-load bearing material. It is NOT intended for use in load bearing, articulating situations such as temporal mandibular joint reconstruction.

6. **Technological Characteristics**:

The modified Titanium Reinforced Configurations of GORE-TEX Regenerative Material have been designed according to the same five design criteria as the predicate device, GORE-TEX Periodontal Material -- Titanium Reinforced Configurations. The additional raw material has reduced the complexity of the manufacturing process.

7. **Assessment of Performance Data**:

Lamination is an important characteristic and testing of the lamination bond strength was performed. The bond values for the modified Titanium Reinforced Configurations are comparable to or better than those of the current Titanium Reinforced Configurations.

8. **Conclusion**:

The modified Titanium Reinforced Configurations of GORE-TEX Regenerative Material are substantially equivalent to the current Titanium Reinforced Configurations of GORE-TEX Regenerative Material in design, manufacturing process, materials, and intended use.